UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,777	12/27/2001	David Strand	005092.00030	1217

22910 7590 10/19/2004

BANNER & WITCOFF, LTD.
28 STATE STREET
28th FLOOR
BOSTON, MA 02109-9601

EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/034,777	STRAND ET AL.
	Examiner	Art Unit
	Brian R. Gordon	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *20-22* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-15-02, 6-12-02,* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS 4-12-02*.

DETAILED ACTION

1. Applicant's election of Group I, claims 1-19 and 23-28 in the reply filed on August 6, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 20-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 6, 2004.

Oath/Declaration

It does not include the each inventor's signature.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 114. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are

required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Allington et al., US 4,911,837.

Allington discloses discloses a mounting and connector arrangement for a chromatographic column. The column 20 (separation conduit with an inlet and outlet) is mounted (potted) inside a housing 18 (fig. 1). As described in column 5, lines 22-26, the column is held in a ferrule arrangement having a ferrule 70, a ring 96 and a frit 92 (as required in claims 10-15).

The ferrule 94 is adapted to fit within the inlet connector 72 and conforms in its outer cone to the ferrule opening at 100 which receives it in a tight engaging fit. The frit sleeve 92 extends into a conforming opening 102 in the inlet connector 72 and rests against a gasket 103 which has a central opening slightly larger than the inlet channel 74. The ferrule nut 96 can be threaded downwardly and move the sleeve portion 104 against the walls of the connector 72 to hold the ferrule 94 in place, thus pressing the gasket 103 between the end 105 of the frit sleeve and the bottom wall of the conforming opening 102 forming a liquid tight seal. The retainer "O" ring 98 prevents the ferrule nut 96 from rattling when it is loose.

7. Claims 16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Brownlee et al. US 4,451,363.

Brownlee discloses a replaceable cartridge column for use in high pressure liquid chromatograph pumping systems including a solid tube having a small bore therethrough carrying a packing material (claim 19).

The cartridge includes the following parts: the tube 10, the packing 12 disposed in a central bore 11 of the tube, end plugs 15,16, and frit filters 18,19. The end plugs and the filters are identical in construction respectively. All parts are cylindrical and axially symmetric. The tube 10 is elongate and is provided with a coaxial bore filled with the particulate packing 12 to form an elution column of predetermined length, in a known manner. The bore opens at each end into a seal recess including a flat bottom 22 transverse to the axis of the tube and a cylindrical outer wall 24. Each end plug is a short section of cylindrical shape and of a diameter which fits into the respective recess.

The outer wall 26 of the plugs are raised slightly to form a pair of spaced circumferential ridges 28,29 which are dimensioned to achieve a partial interference fit with the wall as the plug is inserted so that the plug is difficult to remove upon disassembly of the device as has been encountered due to suction. Each seal plug is itself given a coaxial bore 30 which opens through a coaxial hollow chamber 31 at its inner end, (i.e., toward from the tube) into a frit retaining recess 32. The frit 18,19 is usually of small diameter (i.e., 3/32 inch). As shown in FIGS. 2 and 3, chamber 31 is shaped in the form of a frustum of a cone arranged to form a smooth transition from the smaller diameter of the bore 30, which is made the same as that of the inlet piping 36, to the diameter of the frit chamber 32, which is made the same as the diameter of the bore 11 of the column. The plug is longer than the depth of the sealed recess of the tube so as to extend beyond as indicated at 34 by an amount sufficient to accommodate its yielding and deformation under compression without allowing force to be developed directly in the tube itself as by being in contact with the tube ends or rims. The latter are free of contact and need not be sealed off.

The cartridge is assembled into an end fitting at each end as shown in FIG. 3. Such a fitting assembly includes an end fitting proper given the number 116 and end cap nut 122 into which a tubing supply line 36 from the liquid chromatograph is inserted and retained in place by a radial compression ferrule 140. A seal assembly 118 is contained within the end fitting by suitable means captured in the end of the end fitting itself as by retaining ring 158 bearing upon a positioning washer 159.

8. Claims 16-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. US 4,451,374.

Peterson et al. discloses a chromatographic device comprising a screw-cap or other suitable closure 34. Hollow fibers 36 (separation conduits) are suspended in the reagent, between the points of an effluent in feed connection 38 and out feed connection 40. Each such connection is manufactured as follows: Openings 42 are drilled or otherwise formed in the cap, to which is attached a chromatographic adapter 44. The attachment is made by use of general purpose epoxy glue (potting compound) shown at 46. Chromatographic tubing 48 bringing chromatographic column effluent in is attached to the threaded nipple 50 of adapter 44, using a standard liquid chromatographic connecting nut and ferrule 52, 54. The out feed similarly connects to chromatographic tubing 56 leading to detector 28 through a similarly designated connecting nut 52 and ferrule 54.

The inlet and outlet are in the form of symmetrical parallel projections extending outward for the housing.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-4, 7-9, 23-25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allington et al. as applied to claims 10-15 above, and further in view of Miyake et al., US 5,519,635.

Allington does not specify the inclusion of a memory device in the cartridge.

Miyake et al. disclose an multi-layered (claim 4) apparatus (figure 2) for chemical analysis comprises a main body of analytical apparatus provided with sampling device for sucking sample, liquid controller for transferring the sucked sample and reagents, and detector for measuring the sample, and analytical unit provided with a liquid

connector and a signal connector for connecting to the main body of analytical apparatus, and memory storing at least analytical method, and analysis of the sample is performed by attaching and fixing the analytical unit to said main body of analytical apparatus, transferring at least analytical method stored in the memory to the main body of analytical apparatus, and analyzing the sample in accordance the said analytical method.

The apparatus is a fluid separation conduit cartridge with a fluid separation (chromatographic) column 115 - see e.g. figs. 6-8. Inlet is shown at 1102 and outlet at 1104. The cartridge has memories 112, 113 (see fig. 2). In the cartridge of figs 6-8, the column is of the open channel type, not appropriate to requiring a ferrule structure at its ends. In the fig, 13 version of a cartridge, it would appear that for the fluid separation column 115, ferrules would be needed at the input and output since the input and output tubes are of small cross-section compared with the column diameter.

The pump (claims 24-25) for transferring sample 53 operates to transfer the carrier liquid containing the sample into a chromatocolumn 115 in the analytical unit 11 through the liquid connector 41. The chromatocolumn 115 separates the sample 31 into components, and the separated sample is transferred to the injection portion 114.

At the injection portion 114, the sample and the reagent are merged and transferred to subsequent mixing flow path 116. In the mixing flow path 116, the sample and a designated amount of the reagent are mixed and reacted. Pumps 53, 54 transfer the reacted sample into the main body of the analytical apparatus through the liquid connector 1101 again, and further supply the sample to a detecting flow cell 71. A light

irradiation means 72 and an detector 73 measure the sample in accordance with setting conditions such as absorbing spectrum range and time stored in the memory 112.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Allington to incorporate memories as taught by Miyake et al. in order to allow the chemical analysis methods and results to be stored within the device for automated processing of samples.

13. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, US 5,227,059.

Sheppard discloses a mounting and connector arrangement for a chromatographic column. The column 32 of fig. 2 is held in a ferrule arrangement having a ferrule (plug 46 or locking ferrule 66), a ring (cup 42 or plug 46) and a frit 38. In the fig. 8 embodiment, the ferrule can be considered to be the plug 102, the ring the fitting 74, and the frit is 36.

Sheppard does not disclose that the column is mounted in a housing however, it would been obvious to one of ordinary skill in the art at the time of the invention to recognize that the column may be enclosed within a protective housing to form a cartridge.

14. Claims 1-3, 5-6, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. as applied to claims 16–17 and 19 above, and further in view of Miyake et al.

Peterson et al. do not specify the inclusion of a memory device in the cartridge.

Miyake et al. disclose an multi-layered (claim 4) apparatus (figure 2) for chemical analysis comprises a main body of analytical apparatus provided with sampling device for sucking sample, liquid controller for transferring the sucked sample and reagents, and detector for measuring the sample, and analytical unit provided with a liquid connector and a signal connector for connecting to the main body of analytical apparatus, and memory storing at least analytical method, and analysis of the sample is performed by attaching and fixing the analytical unit to said main body of analytical apparatus, transferring at least analytical method stored in the memory to the main body of analytical apparatus, and analyzing the sample in accordance the said analytical method.

The apparatus is a fluid separation conduit cartridge with a fluid separation (chromatographic) column 115 - see e.g. figs. 6-8. Inlet is shown at 1102 and outlet at 1104. The cartridge has memories 112, 113 (see fig. 2). In the cartridge of figs 6-8, the column is of the open channel type, not appropriate to requiring a ferrule structure at its ends. In the fig, 13 version of a cartridge, it would appear that for the fluid separation column 115, ferrules would be needed at the input and output since the input and output tubes are of small cross-section compared with the column diameter.

The pump (claims 24-25) for transferring sample 53 operates to transfer the carrier liquid containing the sample into a chromatocolumn 115 in the analytical unit 11 through the liquid connector 41. The chromatocolumn 115 separates the sample 31 into components, and the separated sample is transferred to the injection portion 114.

At the injection portion 114, the sample and the reagent are merged and transferred to subsequent mixing flow path 116. In the mixing flow path 116, the sample and a designated amount of the reagent are mixed and reacted. Pumps 53, 54 transfer the reacted sample into the main body of the analytical apparatus through the liquid connector 1101 again, and further supply the sample to a detecting flow cell 71. A light irradiation means 72 and an detector 73 measure the sample in accordance with setting conditions such as absorbing spectrum range and time stored in the memory 112.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Allington to incorporate memories as taught by Miyake et al. in order to allow the chemical analysis methods and results to be stored within the device for automated processing of samples.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hrdina, Jiri; Davis, James C.; Higdon, William R.; Gjerde, and Douglas T. et al. disclose chromatoghy devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

Jill Warden
Supervisory Patent Examiner
Technology Center 1700